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Attorneys for Defendants Watson Laboratories Inc. – Florida, Andrx Corp., Actavis, Inc. and Actavis Pharma, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIPHER PHARMACEUTICALS, INC., GALEPHAR PHARMACEUTICAL RESEARCH, INC., RANBAXY, INC., and RANBAXY PHARMACEUTICALS, INC. Plaintiffs, v. WATSON LABORATORIES, INC. - FLORIDA, ANDRX CORP., ACTAVIS, INC. and ACTAVIS PHARMA, INC. Defendants.	)	Case No. 1:13-6502-JEI-AMD *DOCUMENT FILED ELECTRONICALLY*

DEFENDANTS' ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS

Defendants, Watson Laboratories, Inc. – Florida ("Watson Laboratories"), Andrx Corp. ("Andrx"), Actavis, Inc., and Actavis Pharma, Inc. ("Actavis Pharma") (collectively

"Defendants" or "Actavis"), by and through their undersigned counsel, hereby submit their Answer, Separate Defenses and Counterclaims in response to the Complaint filed by Plaintiffs, Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc., Cipher Pharmaceuticals, Inc. and Galephar Pharmaceutical Research, Inc. (collectively "Plaintiffs").

ANSWER

1. Defendants admit that the Complaint purports to state a cause of action for patent infringement but deny that the allegations have any merit. Defendants aver that Watson Laboratories submitted an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell isotretinoin capsules prior to the expiration of United States Patent No. 8,367,102 ("the '102 patent"). Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 1 of the Complaint.

2. Defendants do not have information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore deny the same.

3. Defendants do not have information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and therefore deny the same.

4. Defendants do not have information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 4 of the Complaint and therefore deny the same.

5. Defendants do not have information or knowledge sufficient to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint and therefore deny the same.

6. Defendants admit that Watson Laboratories (formerly known as Andrx Pharmaceuticals, Inc.) is a corporation organized and existing under the laws of the state of Florida, having a place of business at 495 Orange Drive, Davie Florida 33314. Defendants admit that Watson Laboratories is in the business of developing, manufacturing, and obtaining

regulatory approval of pharmaceutical products. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 6 of the Complaint.

7. Defendants admit that Actavis Pharma is a corporation organized and existing under the laws of the state of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Defendants admit that Actavis Pharma is in the business of selling and distributing pharmaceutical products. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 6 of the Complaint.

8. Defendants admit that Actavis, Inc. is a corporation organized and existing under the laws of the state of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Defendants admit that Actavis, Inc. was formerly known as Watson Pharmaceuticals, Inc. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 8 of the Complaint.

9. Defendants admit that Andrx is a corporation organized and existing under the laws of the state of Delaware, having a place of business at 4955 Orange Drive, Davie, Florida 33314. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 9 of the Complaint.

10. Admitted.

11. Admitted.

12. Defendants admit that Actavis Pharma is a wholly-owned subsidiary of Actavis, Inc.

13. Denied.

14. Defendants admit that Watson Laboratories, Andrx, Actavis, Inc. and Actavis Pharma share at least one common officer and director. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 14 of the Complaint.

15. Defendants admit that until January 23, 2013, Actavis Inc. was operating under the name of Watson Pharmaceuticals, Inc. Defendants admit that Watson Pharmaceuticals, Inc. organized its operations into three business segments: Global Generics, Global Brands, and ANDA Distribution. Except as expressly admitted above, Defendants deny the allegations in Paragraph 15 of the Complaint.

16. Denied.

17. Defendants admit that Actavis, Inc.'s 2012 Annual Report states that Actavis, Inc. "is a leading integrated global specialty pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic, branded generic, brand, biosimilar and over-the-counter ("OTC") pharmaceutical products." Defendants admit that one of Actavis, Inc.'s operational segments is the Actavis Pharma segment, which was previously known as the Global Generics segment. Defendants admit that Actavis Inc.'s 2012 Annual Report provides a list of the "U.S. portfolio of approximately 250 generic pharmaceutical product families" within the Actavis Pharma segment. Except as expressly admitted above, Defendants deny the allegations in Paragraph 17 of the Complaint.

18. Denied.

19. Denied.

20. Denied as stated. Watson Laboratories avers that it did not contest personal jurisdiction in prior New Jersey actions: Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al., Civil Action No. 13-3038; Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, Civil

Action No. 13-1669; Depomed, Inc. v. Actavis Elizabeth LLC, et al., Civil Action No. 12-1358; Warner Chilcott Co., et al. v. Watson Labs., Inc. – Florida, Civil Action No. 11-5989; Abbott Labs., et al. v. Watson Labs., Inc. – Florida, et al., Civil Action No. 10-3241; and Mallinckrodt Inc. v. Watson Labs., Inc. – Florida, et al., Civil Action No. 10-6424). Watson Laboratories avers that it asserted counterclaims in the prior New Jersey action, Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, Civil Action No. 13-1669.

21. Denied as stated. Actavis Inc. avers that it did not contest personal jurisdiction in prior New Jersey actions: Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al., Civil Action No. 13-3038; Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. – Florida, Civil Action No. 12-3084; Depomed, Inc. v. Actavis Elizabeth LLC, et al., Civil Action No. 12-1358; Noven Pharms. v. Watson Labs., Inc., et al., Civil Action No. 11-5997; Shire LLC, et al. v. Amneal Pharms. LLC, et al., Civil Action No. 11-3781; King Pharms. Inc., et al. v. Actavis Inc., et al., Civil Action No. 09-6585; Shire LLC v. Actavis South Atlantic, LLC, et al., Civil Action No. 09-479; King Pharms. Inc., et al. v. Actavis, Inc., et al., Civil Action No. 07-5041; Sanofi-Aventis U.S. LLC, et al. v. Actavis Totowa LLC, et al., Civil Action No. 07-3142). Actavis Inc. avers that it asserted counterclaims in a prior New Jersey action, Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. – Florida, Civil Action No. 12-3084.

22. Denied as stated. Actavis Pharma avers that it did not contest personal jurisdiction in prior New Jersey actions: Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al., Civil Action No. 13-3038; Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. – Florida, Civil Action No. 12-3084; Abbott Labs., et al. v. Watson Labs., Inc., et al., Civil Action No. 10-3241; Teva Neuroscience, Inc., et al. v. Watson Pharma, Inc., et al., Civil Action No. 10-5078; Duramed Pharms. v. Watson Pharma, Inc., Civil Action No. 07-5941; Hoffman La-Roche Inc., et

al. v. Cobalt Pharms. Inc., et al., Civil Action No. 07-4539. Actavis Pharma avers that it asserted counterclaims in a prior New Jersey action, Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. – Florida, Civil Action No. 12-3084.

23. Defendants admit that the Complaint purports to state a cause of action for patent infringement but deny that the allegations have any merit. Defendants will not contest that venue is proper in this Court for the purposes of this Complaint. Except as expressly admitted above, Defendants deny the allegations in Paragraph 23 of the Complaint.

24. Defendants will not contest personal jurisdiction over Watson Laboratories, Andrx, Actavis, Inc. or Actavis Pharma for purposes of this Complaint. Except as expressly admitted above, Defendants deny the allegations in Paragraph 24 of the Complaint.

25. Defendants admit that, on its face, the '102 patent entitled "Pharmaceutical Semi-Solid Composition of Isotretinoin" states that it was issued on February 5, 2013. Defendants admit that, on its face, the '102 patent lists Galephar Pharmaceutical Research, Inc. as an assignee. Defendants admit that Plaintiffs purport to attach a copy of the '102 patent to the Complaint as Exhibit 1. Defendants do not have information or knowledge sufficient to form a belief as to the truth of the remaining allegation in Paragraph 25 of the Complaint and therefore deny the same.

26. Defendants admit that Ranbaxy Inc. is the purported owner of the approved New Drug Application No. 021-951 for isotretinoin capsules, for oral use in 10, 20, 30 and 40 mg dosages, which are sold under the trade name ABSORICA™. Defendants do not have information or knowledge sufficient to form a belief as to the truth of the remaining allegations in Paragraph 26 of the Complaint and therefore deny the same.

27. Defendants admit that the '102 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," with respect to ABSORICA™ in 10, 20, 30 and 40 mg dosages. Except as expressly admitted above, Defendants deny the allegations in Paragraph 27 of the Complaint.

28. Denied.

29. Defendants admit that Watson Laboratories submitted ANDA No. 205063 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market isotretinoin capsules in 10, 20, 30 and 40 mg dosages. Except as expressly admitted above, Defendants deny the allegations in Paragraph 29 of the Complaint.

30. Denied as stated. Defendants aver that Watson Laboratories' ANDA No. 205063 contains bioequivalence data demonstrating the bioequivalence of its isotretinoin capsules product to the ABSORICA™ product.

31. Upon information and belief, Defendants admit the allegations in Paragraph 31.

32. Defendants reallege and incorporate by reference its responses to Paragraphs 1-31 of the Complaint.

33. Denied.

34. Denied as stated. Defendants aver that Watson Laboratories submitted ANDA No. 205063 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to manufacture, use and sell isotretinoin capsules in 10, 20, 30 and 40 mg dosages.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

PLAINTIFFS' PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief set forth in their "Prayer for Relief."

SEPARATE DEFENSES

Without any admission as to burden of proof and expressly reserving their right to assert any additional defenses or counterclaims that discovery may reveal, Defendants state the following defenses:

FIRST SEPARATE DEFENSE

Each purported claim for the relief in the Complaint is barred for failure to state a claim on which relief can be granted.

SECOND SEPARATE DEFENSE

The '102 patent and the claims thereof are invalid for failure to meet the requirements of patentability, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and 282 and/or for improper double patenting.

THIRD SEPARATE DEFENSE

Defendants have not directly or indirectly infringed any valid claim of the '102 patent either literally or under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE

The doctrines of prosecution history estoppel (by argument or by amendment) preclude any finding of infringement of certain claims of the '102 patent, either literally or under the doctrine of equivalents.

FIFTH SEPARATE DEFENSE

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

SIXTH SEPARATE DEFENSE

To the extent that Plaintiffs base a cause of action on the Declaratory Judgment Act seeking a declaratory judgment of alleged future infringement, Defendants assert that a justiciable controversy does not exist and that no legal basis exists for such cause of action.

COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs, Watson Laboratories, Inc. – Florida ("Watson Laboratories"), Andrx Corp. ("Andrx"), Actavis, Inc., and Actavis Pharma, Inc. ("Actavis Pharma") (collectively "Actavis" or "Counterclaim-Plaintiffs"), bring the following Counterclaims against Plaintiffs and Counterclaim-Defendants, Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy Pharmaceuticals"), Cipher Pharmaceuticals, Inc. ("Cipher") and Galephar Pharmaceutical Research, Inc. ("Galephar") (collectively "Counterclaim-Defendants" or "Ranbaxy") and state as follows:

PARTIES

1. Watson Laboratories is a corporation organized and existing under the laws of the state of Florida, having a place of business at 495 Orange Drive, Davie Florida 33314.

2. Andrx is a corporation organized and existing under the laws of the state of Florida, having a principal place of business at 495 Orange Drive, Davie Florida 33314.

3. Actavis, Inc. is a corporation organized and existing under the laws of the state of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. Actavis Pharma is a corporation organized and existing under the laws of the state of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. On information and belief, Counterclaim-Defendant Ranbaxy, Inc. is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 600 College Road East, Princeton, NJ 08540.

6. On information and belief, Counterclaim-Defendant Ranbaxy Pharmaceuticals is a corporation organized and existing under the laws of the state of Florida, having its principal place of business at 9431 Florida Mining Boulevard East, Jacksonville, FL 32257.

7. On information and belief, Counterclaim-Defendant Cipher is a corporation organized and existing under the laws of Canada, having its principal place of business at 5650 Tomken Road, Mississauga, Ontario, Canada.

8. On information and belief, Counterclaim-Defendant Galephar is a corporation organized and existing under the laws of Puerto Rico, having its principal place of business at Carolina, Puerto Rico, 00984-33468.

9. In this lawsuit, Counterclaim-Defendants have alleged in their Complaint that Actavis has committed an act of infringement under 35 U.S.C. § 271(e)(2) by filing an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the manufacture, use or sale of isotretinoin capsules, for oral use in 10, 20, 30 and 40 mg dosages described in Watson Laboratories' ANDA No. 205063 before the expiration of U.S. Patent No. 8,367,102 (the "'102 patent"). Counterclaim-Defendants further alleged in their Complaint that the isotretinoin capsules, for oral use in 10, 20, 30 and 40 mg dosages described in Watson Laboratories' ANDA No. 205063, if sold or marketed, would infringe one or more claims of the '102 patent.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that the counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*. and the Declaratory Judgment Act 28 U.S.C. §§ 2201 and 2202.

11. This Court may declare the rights and other legal relations of the parties involved pursuant to 28 U.S.C. §§ 2201 and 2202, because this case is based on a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that Actavis has not, by the filing of Watson Laboratories ANDA No. 205063 for isotretinoin capsules, for oral use in 10, 20, 30 and 40 mg dosages, infringed any valid claim of the '102 patent, and that the '102 patent is invalid and/or unenforceable.

12. This Court has personal jurisdiction over Counterclaim-Defendants' by virtue of their commencement of an action for patent infringement against Counterclaim-Plaintiffs in this judicial district.

13. Venue for these counterclaims is proper within this judicial district pursuant to 28 U.S.C. § 1391(b), (c) and 1400(b).

COUNT I
(Declaration of No Infringement of the '102 Patent)

14. Actavis repeats and incorporates by reference the allegations set forth in Paragraphs 1-13 of its counterclaims.

15. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between Actavis and Counterclaim-Defendants regarding, *inter alia*, non-infringement of the '102 patent.

16. The filing of an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale of the isotretinoin capsules, for oral use in 10, 20, 30 and 40 mg dosages described in Watson Laboratories' ANDA No. 205063 before the expiration of the '102 patent was not an act of infringement of any valid claim of that patent, either directly or indirectly, literally or under the doctrine of equivalents.

17. Actavis is entitled to a declaration that the filing of an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale of the isotretinoin capsules, for oral use in 10, 20, 30 and 40 mg dosages described in Watson Laboratories' ANDA No. 205063 before the expiration of the '102 patent was not an act of infringement of any valid claim of that patent, either directly or indirectly, literally or under the doctrine of equivalents.

COUNT II
(Declaration of Invalidity of the '102 Patent)

18. Actavis repeats and incorporates by reference the allegations set forth in Paragraphs 1-17 of its counterclaims.

19. At the time of filing of these counterclaims, an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment exists between Actavis and Counterclaim-Defendants regarding, *inter alia*, the validity of the '102 patent.

20. The claims of the '102 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112 and/or 282 and/or for improper double patenting.

21. Actavis is entitled to a declaration that the claims of the '102 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Actavis respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs as follows:

A. Dismissing Plaintiffs' Complaint with prejudice;

B. Declaring that the claims of U.S. Patent No. 8,367,102 are invalid and/or not infringed;

C. Finding that this case is exceptional under 35 U.S.C. § 285 and awarding Actavis its costs, expense and attorneys fees in this action; and

D. Granting any further additional relief as the Court deems just and proper.

Respectfully submitted,

SAIBER LLC
Attorneys for Defendants Watson Laboratories Inc. – Florida, Andrx Corp., Actavis, Inc. and Actavis Pharma, Inc.

Date: December 11, 2013

s/ Arnold B. Calmann

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Defendants Watson Laboratories, Inc. – Florida, Andrx Corp., Actavis, Inc., and Actavis Pharma, Inc., by their undersigned counsel, hereby certify that the matter in controversy is not related to other actions pending in any Court, nor to any pending arbitrations or administrative proceedings.

Dated: December 11, 2013

Respectfully submitted,

SAIBER LLC
Attorneys for Defendants Watson Laboratories Inc. – Florida, Andrx Corp., Actavis, Inc. and Actavis Pharma, Inc.

s/ Arnold B. Calmann
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Defendants Watson Laboratories, Inc. – Florida, Andrx Corp., Actavis, Inc., and Actavis Pharma, Inc., by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: December 11, 2013

Respectfully submitted,

SAIBER LLC
Attorneys for Defendants Watson Laboratories Inc. – Florida, Andrx Corp., Actavis, Inc. and Actavis Pharma, Inc.

s/ Arnold B. Calmann

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